

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended) A system for the reagent-free determination of the concentration of an analyte in living tissue of a patient, the system comprising:

a light transmitter for generating monochromatic primary light having a wavelength of at least 550 nm and at most 900 nm;

a scattered-light percutaneous sensor adapted to be inserted through the skin surface into the skin, wherein a distal end of the percutaneous sensor has a sensor head adapted to pierce the skin, wherein a distal end of the sensor head is enclosed by a semipermeable membrane to define a test volume for containing interstitial fluid from the tissue, wherein the semipermeable membrane prevents admission of macromolecules having a molecular weight above the exclusion limit of the semipermeable membrane to the test volume;

an inbound light guide in which the primary light is conducted through the skin surface into the interior of the body, the primary light having a wavelength of at least 550 nm and at most 900 nm;

a light irradiation surface formed at a distal end of the inbound light guide through which the primary light penetrates into a the test volume of the tissue;

a detection light guide which has at its distal end a light receiving surface through which a secondary light scattered in the test volume penetrates into the detection light guide, wherein the light irradiation surface of the inbound light guide and the light receiving surface of the detection light guide are adapted to be located subcutaneously so that the test volume contains the interstitial fluid;

a wavelength-sensitive detection device connected to the detection light guide for detection of Raman-scattered components of the secondary light; and

an evaluation device for determining the concentration of the analyte from the Raman-scattered components of the secondary light.

2. (Original) The system according to claim 1, wherein the analyte is glucose.

Claim 3 (Canceled).

4. (Original) The system according to claim 1, wherein the primary light is irradiated with only one wavelength, the wavelength being such that a spontaneous Raman scattering occurs.

5. (Previously Presented) The system according to claim 1, wherein the wavelength of the primary light is at most 800 nm.

6. (Original) The system according to claim 1, wherein a multivariate analysis method is used for determining the concentration of the analyte from the Raman spectrum.

Claim 7 (Canceled).

8. (Currently amended) The system according to claim 7, wherein the exclusion limit of the semipermeable membrane is at most 50 kDa.

9. (Currently amended) The system according to claim 1, wherein ~~the percutaneous sensor includes a~~ the detection light guide is in the form of a ring which surrounds a central inbound light guide.

10. (Original) The system according to claim 9, wherein the detection light guide ring is formed by a plurality of optical fibers arranged in a ring pattern around the inbound light guide.

11. (Original) The system according to claim 9, wherein the detection light guide ring is formed by a fiber-optic tube which surrounds the inbound light guide.

12. (Currently amended) A system for the reagent-free determination of the concentration of an analyte in living tissue of a patient, the system comprising:

a light transmitter for generating monochromatic primary light having a wavelength of at least 550 nm and at most 900 nm;

a scattered-light percutaneous sensor adapted to be inserted through the skin surface into the skin, wherein a distal end of the percutaneous sensor has a sensor head, the sensor head defining a test volume for containing interstitial fluid from the tissue;

an inbound light guide in which the primary light is conducted through the skin surface into the interior of the body;

a light irradiation surface formed at a distal end of the inbound light guide through which the primary light penetrates into the test volume;

a detection light guide which has at its distal end a light receiving surface through which a secondary light scattered in the test volume penetrates into the detection light guide, wherein the light irradiation surface of the inbound light guide and the light receiving surface of the detection light guide are adapted to be located subcutaneously so that the test volume contains the interstitial fluid;

a wavelength-sensitive detection device connected to the detection light guide for detection of Raman-scattered components of the secondary light;

an evaluation device for determining the concentration of the analyte from the Raman-scattered components of the secondary light;

The system according to claim 1, wherein:

wherein the sensor head includes a reflective surface configured and arranged positioned around the test volume to reflect the Raman-scattered components of the secondary light towards the light receiving surface of the detection light guide; and

wherein the reflective surface is designed and arranged positioned to not reflect the primary light emitted from the inbound light guide towards the light receiving surface of the detection light guide.

13. (Original) The system according to claim 12, wherein the reflective surface is formed by a boundary surface of the detection light guide on the side of the detection light guide which faces away from the primary light beam emerging from the light irradiation surface.

14. (Original) The system according to claim 13, wherein the boundary surface is coated with a filter coating which allows the primary light to pass through but reflects the Raman-scattered light.

15. (Original) The system according to claim 13, wherein the reflective surface is inclined at an angle (β) between 10° and 40° to the axis (A) of the primary light beam emerging from the light irradiation surface.

16. (Original) The system according to claim 13, wherein the distal end of the detection light guide is designed as a transparent ring segment body having a conical reflective surface and a central recess, the recess being aligned with the inbound light guide.

17. (Original) The system according to claim 12, wherein the reflective surface is formed by a surface of a reflector element which forms a lateral limitation of the test volume and the reflective surface is inclined to the axis (A) of the primary light beam emerging from the light irradiation surface such that the scattered secondary light is concentrated towards the light receiving surface of the detection light guide.

18. (Original) The system according to claim 17, wherein the reflective surface is inclined at an angle (α) of less than 10° to the axis (A) of the primary light beam emerging from the light irradiation surface.

19. (Original) The system according to claim 17, wherein the reflector element is a reflecting sleeve surrounding the primary light beam.

20. (Previously Presented) The system according to claim 1, wherein the percutaneous sensor has a diameter of at most 2 mm.

21. (Previously Presented) The system according to claim 1, wherein the wavelength of the primary light is at most 600 nm.

22. (Currently amended) The system according to claim 7_1, wherein the exclusion limit of the semipermeable membrane is at most 20 kDa.

23. (Previously Presented) The system according to claim 1, wherein the percutaneous sensor has a diameter of at most 1 mm.

24. (Previously Presented) The system according to claim 1, wherein the percutaneous sensor has a diameter of at most 0.5 mm.

25. (Currently amended) A method, comprising:

inserting a sensor head of a scattered-light percutaneous sensor into skin, wherein the sensor head includes a light irradiation surface and a light receiving surface, wherein said inserting includes locating the light irradiation surface and the light receiving surface in subcutaneous connective tissue of the skin so that a test volume of the sensor head contains interstitial fluid, wherein the sensor head is enclosed by a semipermeable membrane to define the test volume;

shining a monochromatic primary light that has wavelength of at least 550 nm and at most 900 nm from the light irradiation surface of the sensor head into the test volume containing the interstitial fluid;

receiving a secondary light scattered from the test volume containing the interstitial fluid at the light receiving surface of the sensor head;

detecting Raman-scattered components of the secondary light from the secondary surface with a wavelength-sensitive detection device; and

determining concentration of analyte in the test volume from the Raman-scattered components of the secondary light; and

reducing fluorescence interference by preventing access of macromolecules that have a molecular weight greater than 50 kDa to the test volume with the semipermeable membrane of the sensor head.

Claim 26 (Canceled).

27. (Currently amended) The method of claim 26 25, further comprising:

suppressing the fluorescence interference by limiting the spectral range of the primary light between 550 nm and 750 nm during said shining.

28. (Currently amended) The method of claim 26 25, wherein the analyte is non-fluorescing and has a molecular weight of at most 50 kDa.

29. (Previously Presented) The method of claim 25, wherein said determining the concentration of the analyte includes determining glucose concentration.

30. (Previously Presented) The method of claim 25, further comprising:
reducing interference from the primary light, wherein said reducing interference from the primary light includes

- directing the primary light from the light irradiation surface through a recess in a reflector of the sensor head, and
- reflecting the secondary light scattered from the test volume with the reflector to the wavelength-sensitive detection device.

31. (Previously Presented) The method of claim 25, wherein said determining the concentration of the analyte includes multivariate analysis.

32. (New) The method of claim 25, wherein:
the analyte is glucose; and
said determining includes determining glucose levels by conventional Raman spectroscopy.

33. (New) The method of claim 25, providing a readout of the concentration.

34. (New) The system according to claim 1, wherein:
the sensor head includes a reflective surface configured and arranged to reflect the Raman-scattered components of the secondary light towards the light receiving surface of the detection light guide; and
the reflective surface is designed and arranged to not reflect the primary light emitted from the inbound light guide towards the light receiving surface of the detection light guide.

35. (New) The system according to claim 12, wherein a distal end of the sensor head is enclosed by a semipermeable membrane.